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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,222	10/01/2003	Robert A. Holton	FSUM 10462.50	9712
321	7590	08/14/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			OWENS, AMELIA A	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,222

Applicant(s)

HOLTON, ROBERT A.

Examiner

Amelia A. Owens

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-89,91-119,122-124,127-133,137-141,144 and 146-175 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-89,91-119,122-124,127-133,137-141,144,146-161,163-174 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-89,91-119,122-124,127-133,137-141,144,146-175 are pending.

Double Patenting

2. The ODP rejection of claims 1-164 over 6649632 is dropped as a terminal disclaimer has been filed and accepted and claims have been canceled.
3. The ODP rejection over 6780879 is dropped, as applicant's remarks are persuasive.
4. Claims 1-89,91-119,122-124,127-133,137-141,144,146-175 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-33 of U.S. Patent No. 6638973. Although the conflicting claims are not identical, they are not patentably distinct from each other because USP 973 generically discloses taxane compounds as are instantly claimed and their antitumor/neoplastic use.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the genus of the above references in order to obtain additional beneficial antitumor agents. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of the above references in the expectation of obtaining a useful compound to treat tumors as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

See for example claims 14,20, example 18, columns 112-114.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1,91-97,109-112,127-130,137-138,165 are rejected under 35 U.S.C. 102(b) as being anticipated by Holton 5227400 that teach species according to the invention. See examples

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1,2. Note when R10 =OOCR10a and R10a is hydrocarblyl it reads on OAc of the reference; X5 being COX10 and X10 being hydrocarblyl reads on CO-phenyl.

6. Claims 1,91-97,109-112,127-130,137-138,165 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5250683 example 6 where the X3 position is methylenedioxyphenyl that is a heterocycle group.

7. Claims 1,91-97,109-112,127-130,137-138,165 are rejected under 35 U.S.C. 102(b) as being anticipated by Georg et al, Heteroaromatic Taxol Analogues: The Chemistry and Biological Activities of 3'-Furyl and 3'-Pyridyl Substituted Taxanes, Bioorganic & Medicinal Chemistry Letters, 4(11), 9 June 1994, abstract. See species depicted.

8. Claims 1,91-97,109-112,127-130,137-138,165 rejected under 35 U.S.C. 102(b) as being anticipated by Li et al Synthesis and Biological Evaluation of C-3'-Modified Analogs of 9(R) - dihydrotaxol, J. Med. Chem. 1994,37,2655-2663 teach species RN 160238-30-2; 160238-36-8. Note X5 is COOX10 and X10 is hydrocarblyl(t-butyl); X3 is thiazolyl or 2,2-dimethyl-1,3-dioxol-4-yl which are both heterocycles.

9. Claims 1,91-97,109-112,127-130,137-138,165 rejected under 35 U.S.C. 102(b) as being anticipated by USP 5489601 examples 1-3. Note X3 is pyridyl and X5 is COOX10 and X10 is hydrocarblyl(t-butyl).

10. Claims 1,91-97,109-112,127-130,137-138,165 are rejected under 35 U.S.C. 102(b) as being anticipated by Holton WO 94/20485 teach species according to the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 1-89,91-119,122-124,127-133,137-141,144,146-161,163-174 are rejected under 35 U.S.C. 103(a) as being unpatentable over *references in above paragraphs 4-9* that generically disclose taxane compounds as are instantly claimed and their antitumor/neoplastic use.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the genus of the above references in order to obtain additional beneficial antitumor agents. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of the above references in the expectation of obtaining a useful compound to treat tumors as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

See for example USP 5227400 from paragraph 4, where the reference teaches variable Z = OT1 and T1 = COT2 and T2 – C1-C6 alkyl which encompasses the ethyl, propyl, etc. of the claims. Note T2 also includes alkenyl, alkynyl and aryl.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 165 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim refers to esters, ethers, acetals, ketals which are all groups with no apparent bond available to attach to the molecule. The term thiol is ambiguous as it just indicates the presence of sulfur usually to replace an oxygen. What sulfur containing group does applicant intend.

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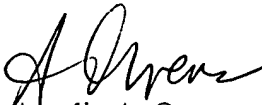
Certain Observations

13. The references relied upon were cited by applicant.
14. Claims 162,175 are allowable. A terminal disclaimer has been filed over 6649632.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Amelia A. Owens
Primary Examiner
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